REMARKS

Claims 1 to 11 as set forth in Appendix II of this paper are now pending in this case. Claims 1 to 9 have been amended, as indicated in the Listing of Claims set forth in Appendix I of this paper.

Accordingly, applicants have made some editorial changes in Claims 1 to 9 to better bring out that the claimed invention resides in a crystalline form of choline ascorbate. No new matter has been added.

The Examiner has rejected Claims 1 to 11 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of ***Blackett et al.*** (**US 2,774,759**) when taken in view of the disclosure of ***Klein et al.*** (**US 2,870,198**) and further in view of the disclosure of ***Spires*** (**US 4,394,377**).

Applicants' invention relates to a new physical form of choline ascorbate, ie. a crystalline form. At the time applicants made their invention, the art merely showed choline ascorbate as a colorless viscous liquid[1)], with no suggestion that a crystalline form of choline ascorbate exists.

The teaching of ***Blackett et al.*** relates to an improved process for preparing choline salts which essentially aims at improving the color of the salts[2)]. It is respectfully noted that ***Blackett et al.*** do not mention choline ascorbate and, therefore, fail to suggest or imply any particular physical form of choline ascorbate. Moreover, at the time applicants' made their invention a person of ordinary skill was not motivated to prepare choline ascorbate by the process of ***Blackett et al.*** since the known product, in accordance with ***Hoffman***'s teaching in ***US 2,823,166***, is colorless. An improvement of the color of the known choline ascorbate is therefore unnecessary.

Essentially the same applies where the teaching of ***Klein et al.*** is concerned since ***Klein et al.*** equally fail tom mention choline ascorbate and, therefore, equally fail to suggest or imply any particular physical form of choline ascorbate. Moreover, ***Hoffman*** discloses anhydrous choline ascorbate the analytical data of which

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1) Note, for example, ***Hoffman***'s disclosure in col. 2, indicated line 65, to col. 3, indicated line 69, of ***US 2,823,166***, which is referenced by ***Spires*** in col. 4, indicated lines 8 to 13, of ***US 4,394,377***.

2) Note, for example, col. 2, indicated lines 38 to 41, of ***US 2,774,759***.

compare closely with the theoretical data[3]. At the time applicants made their invention a person of ordinary skill in the art had therefore no incentive to improve the purity or to obtain the anhydrous form of choline ascorbate in accordance with the process of ***Klein et al***. It is also respectfully noted in this context that a statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" is not sufficient to establish a prima facie case of obviousness without some objective reason to make the modification which is necessary[4], and the mere fact that the prior art may be modified in some manner so as to result in the invention as claimed does not render such a modification obvious where the prior art fails to suggest the desirability of such a modification[5].

Spires merely states *"The preparation of the several recited choline salts is briefly recited here, though all can be obtained from commercial manufacturers. Choline ascorbate can be prepared from choline and ascorbic acid in methanol according to the procedure set out in U.S. Pat. No. 2,823,166* **[Hoffman]**" (*col. 4, indicated lines 10 to 13, of* **US 4,394,377**, *emphasis added*). Accordingly, ***Spires*** equally fails to suggest or imply that choline ascorbate exists in a form different from the colorless, heavy viscous liquid which is described by ***Hoffman***.

The prior art neither suggests nor implies that choline ascorbate is susceptible to crystallization or that a crystalline form of choline ascorbate even exists. As emphasized by the Court in *In re Cofer*[6], a new physical form of a compound is a part of the "subject matter as a whole" referenced in Section 103(a). Since the prior art fails to teach or suggest the existence of choline ascorbate in a crystalline form, it clearly falls short from rendering applicants' invention "as a whole" prima facie obvious within the meaning of Section 103(a). The Court's holding in *In re Cofer* is deemed particularly suitable as precedent for the present case because there, as

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3) Compare, for example, the data in columns 2 and 4 of Table 1, col. 3, indicated lines 35 to 47, of ***US 2,823,166***.

4) Ex parte Levengood, 28 USPQ2d 1300 (BPAI 1993); In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (CAFC 2000)

5) In re Fritch, 972 F.2d 1260, 23 USPQ2d 1780, 1783-84 (CAFC 1992); In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (CAFC 1984)

6) 354 F.2d 664, 148 USPQ 268 (CCPA 1966)

here, the prior art merely described a compound as a viscous liquid and the claims related to the compound in form of crystals. The Court found that the description of a liquid does not suggest the existence of a crystalline form, and reversed the Board's rejection which had been based on the position that the liquid form of the compound rendered the claimed crystalline form of the compound *prima facie* obvious.

Favorable reconsideration of the Examiner's position and withdrawal of the rejection of Claims 1 to 11 under 35 U.S.C. §103(a) is, therefore, respectfully solicited.

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Respectfully submitted,
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Encl.: THE LISTING OF CLAIMS (Appendix I)
THE AMENDED CLAIMS (Appendix II)

HBK/BAS

APPENDIX I:

THE LISTING OF CLAIMS (version with markings):

1. (*currently amended*) A [~~crystalline~~] choline ascorbate in form of crystals.

2. (*currently amended*) [~~A crystalline~~] The choline ascorbate crystals as claimed in claim 1, [~~in the form of~~] wherein the crystals are free from water of crystallization.

3. (*currently amended*) [~~A crystalline~~] The choline ascorbate crystals as claimed in claim 1, [~~wherein the~~] having diffraction lines at d = 3.80 Å and 4.55 Å which are most intense in [~~the~~] a range between 3.40 and 4.70 Å in [~~the~~] a 2 Θ X-ray powder diffractogram.

4. (*currently amended*) [~~A crystalline~~] The choline ascorbate crystals as claimed in claim 3, [~~wherein the~~] having an intensity ratio of the diffraction lines at d = 3.80 Å and d = 4.55 Å [~~is~~] of at least 0.5.

5. (*currently amended*) [~~A crystalline~~] The choline ascorbate crystals as claimed in claim 3, [~~wherein the~~] having an intensity ratio of the diffraction lines at d = 3.80 Å and d = 4.55 Å [~~is~~] of at least 0.4.

6. (*currently amended*) A process for preparing [~~crystalline~~] choline ascorbate [~~by~~] in form of crystals, which comprises reacting ascorbic acid with triethylamine and ethylene oxide, [~~which comprises~~] and carrying out the reaction in [~~the~~] a temperature range from -10°C to 40°C.

7. (*currently amended*) [~~A~~] The process [~~as claimed in~~] of claim 6, [~~wherein the reaction~~] which is carried out in a water-miscible organic solvent.

8. (*currently amended*) [~~A~~] The process [~~as claimed in~~] of claim 7, wherein the choline ascorbate is crystallized in the solvent used for the reaction.

9. (*currently amended*) A choline ascorbate in form of crystals obtainable by [~~a~~] the process defined according to claim 6.

10. (*previously presented*) Drugs comprising the choline ascorbate claimed in claim 1.

11. (*previously presented*) Additives in foods, additives in animal feeds or food supplements comprising the choline ascorbate claimed in claim 1.

APPENDIX II:

THE AMENDED CLAIMS (clean version):

1. (*currently amended*) A choline ascorbate in form of crystals.

2. (*currently amended*) The choline ascorbate crystals as claimed in claim 1, wherein the crystals are free from water of crystallization.

3. (*currently amended*) The choline ascorbate crystals as claimed in claim 1, having diffraction lines at d = 3.80 Å and 4.55 Å which are most intense in a range between 3.40 and 4.70 Å in a 2 Θ X-ray powder diffractogram.

4. (*currently amended*) The choline ascorbate crystals as claimed in claim 3, having an intensity ratio of the diffraction lines at d = 3.80 Å and d = 4.55 Å of at least 0.5.

5. (*currently amended*) The choline ascorbate crystals as claimed in claim 3, having an intensity ratio of the diffraction lines at d = 3.80 Å and d = 4.55 Å of at least 0.4.

6. (*currently amended*) A process for preparing choline ascorbate in form of crystals, which comprises reacting ascorbic acid with triethylamine and ethylene oxide, and carrying out the reaction in a temperature range from -10°C to 40°C.

7. (*currently amended*) The process of claim 6, which is carried out in a water-miscible organic solvent.

8. (*currently amended*) The process of claim 7, wherein the choline ascorbate is crystallized in the solvent used for the reaction.

9. (*currently amended*) A choline ascorbate in form of crystals obtainable by the process defined according to claim 6.

10. (*previously presented*) Drugs comprising the choline ascorbate claimed in claim 1.

11. (*previously presented*) Additives in foods, additives in animal feeds or food supplements comprising the choline ascorbate claimed in claim 1.